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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,901	07/16/2003	Kevin S. Brandt	FC-8-C3	3345

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Heska Corporation
Intellectual Property Dept
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EXAMINER	
VOGEL, NANCY S	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,901	BRANDT ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *9-17,19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, and the sequence SEQ ID NO:26, in the reply filed on 12/20/04 is acknowledged. The traversal is on the ground(s) that it would not be a burden to examine all of the claims. This is not found persuasive because the search required for the examination of all of the claims would indeed be burdensome, since each group set forth in the previous requirement encompasses divergent subject matter, and since there are thousands of nucleic acid molecules disclosed in the specification and encompassed by the claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-17, 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/20/04. Applicant should amend the claims to be limited to the nucleic acid whose sequence is set forth in SEQ ID NO:26.

Claim Objections

Claim 1 is objected to because of the following informalities:

Claim 1 contains abbreviations (HMT, HNC), which should be spelled out in the first occurrence for clarity.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-8 and 18 (as applied to the elected species) are directed to an isolated nucleic acid molecule having the nucleotide sequence of SEQ ID NO:26, hybridization variants thereof, recombinant virus comprising said nucleic acid molecule, recombinant host cells comprising said nucleic acid molecule, and compositions comprising said nucleic acid molecule and an excipient.

The specification discloses a nucleic acid which comprises the nucleic sequence SEQ ID NO:26. The specification does not disclose any significant homology to other prior art nucleic acids. The instant specification does not disclose any additional information regarding this nucleic acid such as the encoded protein's subcellular location, timing of regulation of expression during cellular differentiation, regulation methods, and what physiological significance is possessed by the nucleic acid or a protein which it may encode. The specification generally asserts that the nucleic acids disclosed therein are useful in encoding proteins of interest. However, this is a utility known for any nucleic acid expressed in any tissue, and therefore is not substantial and specific. The specification also generally asserts that the disclosed nucleic acids are useful in the protection of an animal from flea infestation, stating that "such a nucleic acid molecule can be, or encode, an antisense RNA, a molecule capable of triple helix

formation, a ribozyme, or other nucleic acid-based drug compound. In additional embodiments, a nucleic acid molecule of the present invention can encode a protective protein (e.g., an HMT or HNC protein of the present invention), the nucleic acid molecule being delivered to the animal, for example, by direct injection (i.e., as a genetic vaccine) or in a vehicle such as a recombinant virus vaccine or a recombinant cell vaccine" (page 49-50). However, this asserted use does not meet the three-pronged requirement of 35 USC 101 regarding utility, namely that the asserted utility be credible, specific and substantial. This utility is not specific to the nucleic acid of SEQ ID NO:26, but rather is apparently being applied to any and all nucleic acids disclosed by the specification, which number in the thousands. Therefore this asserted utility is not substantial or specific. A substantial utility, by definition, is a utility that defines "real world" use, and a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 18 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible,

substantial or specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, even if the specification taught how to use the claimed nucleic acid or the polypeptide encoded thereby, enablement would not be commensurate in scope with claims 3-7 and 18 which encompass hybridization variants of SEQ ID NO:26 under specified conditions, and variants having at least 70% identity to SEQ ID NO:26. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are directed to % variants and hybridization variants of the nucleic acid of SEQ ID NO: 26, which encompasses on any or all variants meeting the sequence limitation. The specification provides no guidance or working examples as to how the skilled artisan could use a nucleic acid encoding an inactive polypeptide variant encoded by these nucleic acids, or the variant nucleic acids themselves, as no functional limitation is associated with the variants in the claims.

Further, with respect to the hybridization variants of said nucleotides, the claims read on any or all nucleotides hybridizing with SEQ ID NO: 26 under the specified conditions. It is well known in the art that hybridization will occur even under stringent conditions if there is only local identity between two molecules whose sequences might be totally divergent outside of that region. Such hybridized molecules may encode proteins that share a common functional property with the polypeptide encoded by SEQ

ID NO:26, yet have other distinct biological functions; in addition, the nucleic acid variants may have distinct properties when used in therapeutic compositions. The specification does not define a specific hybridization condition for obtaining the claimed species, or working examples of any such variants, which would be within the limitations of the claims. Therefore, it would require undue experimentation in order to make and use the claimed invention in its full scope.

Due to the large quantity of experimentation necessary to determine how to use the nucleic acids encoding inoperative polypeptides, or nucleic acids which are inoperative when introduced into an animal for therapeutic purposes, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which embrace a broad class of structurally diverse variants and fragments, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 3-8 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a nucleic acid having at least 70% sequence identity with a particularly disclosed sequence, SEQ ID NO: 26, or hybridization variants of SEQ

ID NO:26 under specified conditions. The claims do not require that the nucleic acids or any polypeptides encoded thereby, possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature. Thus the claims are drawn to a genus of nucleic acids that is defined only by sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete of partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity. There is not identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath V. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acids, and therefore conception is not achieved until reduction to

practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Col. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated nucleic acid set forth in SEQ ID NO:26, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. 112, first paragraph. This is particularly important in the absence of a specific known activity. Applicant is reminded that *Vas-Cath* makes clear that written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NANCY VOGEL, PH.D.
PATENT EXAMINER